



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0291; FRL-10012-67]

Diquat; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of diquat in or on pea and bean, dry and shelled, except soybean, subgroup 6C. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0291, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at

http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCFA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0291 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0291, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed

information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of September 15, 2017 (82 FR 43354) (FRL-9965-43), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E8571) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide diquat in or on pea and bean, dry and shelled, except soybean, subgroup 6C at 0.08 parts per million (ppm). In the *Federal Register* of May 7, 2018 (83 FR 20008) (FRL-9976-34), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing a correction to the pesticide petition (PP 7E8571) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The corrected petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide diquat in or on pea and bean, dry and shelled, except soybean, subgroup 6C at 0.9 parts per million (ppm). Both documents referenced a summary of the petition prepared by Syngenta, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCFA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCFA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all

anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCFA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCFA section 408(b)(2)(D), and the factors specified in FFDCFA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for diquat including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with diquat follows.

EPA conducted a human health risk assessment to evaluate the safety of the requested tolerances. *See* “Diquat. Human Health Risk Assessment for the Establishment of a Tolerance without U.S. Registration for Residues in/on Crop Subgroup 6C Dried Shelled Pea and Bean (Except Soybean)” (July 21, 2020), which is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA-HQ-OPP-2017-0291. In that document, EPA evaluated the available hazard and exposure data to conduct dietary, residential, and aggregate assessment to determine risk to human health and refers back to the discussions of the hazard profile, residue chemistry database, and residential exposures contained in the previous human health risk assessment conducted for registration review, “Diquat Dibromide: Draft Human Health Risk Assessment for Registration Review” (Sept. 17, 2015) (“Registration Review RA”), which can be found in the docket EPA-

HQ-OPP-2009-0846 and is included in this docket. Based on the discussion in the Registration Review RA, the Agency has determined that there is reliable data to support the use of a 1X margin of safety for the protection of infants and children.

While the acute dietary assessment was unrefined, using tolerance-level residues and 100% crop treated (PCT), the chronic dietary assessment was more refined and used anticipated-residue levels from magnitude of residue studies for crops irrigated with water treated with diquat in conjunction with estimates of percentage of crops irrigated. Default processing factors were also used in both the acute and chronic dietary analyses and both analyses incorporated the Office of Water's Maximum Contaminant Level (0.02 ppm) as a worst-case drinking water estimate due to domestic uses of diquat. EPA's aggregate exposure assessment incorporated the total dietary exposure, as well as exposure from residential sources, which is not impacted by the tolerance without U.S. registrations on pea and bean, dry and shelled, except soybean, subgroup 6C and thus has not changed since the Registration Review RA.

Acute aggregate dietary risks (food and water) are below the Agency's level of concern of 100% of the acute population adjusted dose: 1.4% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Chronic dietary risks are below the Agency's level of concern of 100% of the chronic population adjusted dose (cPAD): 41% of the cPAD for children 1 to 2 years old the population group receiving the greatest exposure. For the short-/intermediate-term aggregate risk assessment, potential residential exposures were combined with dietary exposures. For both adults and children 1 to <2, exposures from high-contact activities on outdoor treated turf resulted in the highest residential exposures for aggregate consideration. Short-/intermediate-term aggregate margins of exposure (MOEs) are greater than the LOC of 100 (2,010 for adults and 280 for children 1 to 2 years old) and are

therefore not of concern. Due to the lack of carcinogenicity, the Agency concludes that exposure is not expected to pose a cancer risk to the U.S. population.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to diquat residues.

IV. Other Considerations

A. Analytical enforcement methodology

Adequate enforcement methodology (analytical method number RAM 272/02 “The Determination of Residues of Paraquat and Diquat in crops and Soil – A High Performance Liquid Chromatographic Method”) is available to enforce the tolerance expression.

B. International residue limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCa section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established an MRL for diquat in or on dry pea (subgroup) at 0.9 ppm. This MRL is the same as the tolerance established for diquat in this decision. However, Codex

has established MRLs for diquat in or on dry bean (subgroup) at 0.4 ppm. Canada has established MRLs for both dry pea and dry bean at 0.9 ppm.

C. Response to comments

Two general comments were received on the notices of filing expressing general concern about the potential of pesticide residues in food, although none provided any substantive information to take into consideration in EPA's safety assessment. The FFDCA authorizes EPA to establish tolerances that permit certain levels of pesticide residues in or on food when the Agency can determine that such residues are safe. EPA has made that determination for the tolerances subject to this action; commenters provided no information relevant to that conclusion.

V. Conclusion

Therefore, tolerances are established for residues of diquat in or on pea and bean, dry and shelled, except soybean, subgroup 6C at 0.9 ppm and the tolerance expression is being updated.

Also, in accordance with EPA's policy to update its tolerance expressions where applicable, EPA is revising the tolerance expression to clarify that (1) as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of diquat not specifically mentioned; and (2) compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment because public comment is not necessary since the change is merely intended to clarify the existing tolerance expression and has no substantive effect on the tolerance.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition

submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255,

August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 16, 2020.

Marietta Echeverria,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180 — TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.226, amend paragraph (a)(1) by:

a. Revising the introductory text and adding a heading for the table; and

b. Adding in alphabetical order to the table the entry for “Pea and bean, dry and shelled, except soybean, subgroup 6C” and footnote 1.

The revision and additions read as follows:

§ 180.226 Diquat; tolerances for residues.

(a) * * *

(1) Tolerances are established for the residues of the herbicide diquat, including its metabolites and degradates, in or on the commodities in Table 1 to this paragraph (a)(1) resulting from the application of the dibromide salt of diquat. Compliance with the tolerance levels specified in Table 1 to this paragraph (a)(1) is to be determined by measuring only diquat (6,7-dihydrodipyrido[1,2-a:2',1'-c]pyrazinediium):

Table 1 to paragraph (a)(1)

Commodity	Parts per million
* * * * *	
Pea and bean, dry and shelled, except soybean, subgroup 6C ¹	0.9
* * * * *	

¹There are no U.S. registrations for these commodities as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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[FR Doc. 2020-22190 Filed: 10/21/2020 8:45 am; Publication Date: 10/22/2020]